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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/719,295	11/21/2003	Carl Berger	163.1.004	3011

7590 12/07/2006

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EXAMINER

SCHLIENTZ, NATHAN W

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 12/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/719,295	Applicant(s) BERGER, CARL	
	Examiner Nathan W. Schlientz	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 5-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 5-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>08/03/06</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1616. Examiner Nathan Schlientz can be reached at 571-272-9924.
2. Claims 3 and 4 have been cancelled by applicant in an amendment mailed 03 August 2006.
3. Claims 1, 2, and 5-25 are pending. No claim is allowed at this time.

Response to Arguments

4. Applicant's arguments with respect to claims 1-25 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1,148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 1, 2, 5-14 and 16-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Musser et al. (Nature, 11 April 2002, 416, 599-600).

Applicant claims:

8. The Applicant claims a method of reducing the nicotine content of a tobacco plant through application of a sufficient amount of glucose oxidase to result in a non-addictive level of nicotine in the CNS blood plasma of the user. The tobacco plant is *Nicotiana tabacum*, *Nicotiana rustica*, or *Nicotiana glutinosa*, and the glucose oxidase is produced by *Helicoverpa zea*. Also, the non-addictive level of nicotine is less than about 5 ng/ml in the CNS blood plasma. Applicant also claims the above method wherein the glucose oxidase is in combination with a carrier.

Determination of the scope and content of the prior art

(MPEP 2141.01)

9. Musser et al. teach the saliva of the caterpillar *Helicoverpa zea* can reduce the amount of toxic nicotine released by the tobacco plant *Nicotiana tabacum* (page 599, first paragraph). Musser et al. further teach feeding by caterpillars with intact spinnerets, the principal secretory structures of the labial salivary glands of *Helicoverpa zea*, reduced foliar nicotine levels by over 26% compared with the control (page 599, middle column, lines 6-10). Musser et al. also teach treatment of individual leaves with one of four preparations: active purified glucose oxidase, unpurified salivary-gland

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extract, inactivated (autoclaved) purified glucose oxidase, or water, wherein leaves treated with salivary extract received 20 micrograms glucose oxidase in total (page 599, third column, lines 16-22). Musser et al. also teach each wound on the plant received 10 microliters of water (page 599, third column, lines 22-23), which according to the specification would be a suitable carrier (page 11, lines 21-22).

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

10. Musser et al. do not teach the desired amount of treatment required to obtain a non-addictive level of nicotine. However, the applicant uses glucose oxidase that comes from the exact same source as Musser et al., *Helicoverpa zea*. Also, the applicant is treating the exact same species plant as Musser et al., *Nicotiana tabacum*. The applicant clearly states that repeated administration of the glucose oxidase may be required to sequentially lower the level of nicotine to the non-addictive level (specification, page 14, lines 8-10 and claim 20). To determine the number of treatments with glucose oxidase, or the amount of glucose oxidase required to reduce the level of nicotine to the desired level would require routine experimentation.

11. The examiner respectfully points out the following from MPEP 2144.05: "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955); see also Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed

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set of percentage ranges is the optimum combination of percentages."); *In re Hoeschele*, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969); *Merck & Co. Inc. v. Biocraft Laboratories Inc.*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989); *In re Kulling*, 897 F.2d 1147, 14 USPQ2d 1056 (Fed.Cir. 1990); and *In re Geisler*, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997).

Finding of *prima facie* obviousness

Rational and Motivation (MPEP 2142-43)

12. Therefore, it would have been *prima facie* obvious for one skilled in the art at the time of the invention to repeatedly use glucose oxidase from *Helicoverpa zea*, or a biochemical source, to reduce the amount of nicotine in *Nicotiana tabacum* to a non-addictive level.

13. From the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in practicing the claimed invention, because determining the amount of glucose oxidase required to reduce the level of nicotine to a non-addictive level would have been routine experimentation. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

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14. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Musser et al. as applied to claims 1, 2, 5-14 and 16-20 above.

Applicant claims:

15. The Applicant claims a method of reducing the nicotine content of a genetically modified tobacco plant through application of a sufficient amount of glucose oxidase to result in a non-addictive level of nicotine in the CNS blood plasma of the user. The genetically modified tobacco plant exhibits a reduced level of nicotine as compared to non-genetically modified tobacco plants.

Determination of the scope and content of the prior art

(MPEP 2141.01)

16. The teachings of Musser et al. are discussed above.

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

17. Musser et al. do not teach applying glucose oxidase to a genetically modified tobacco plant that exhibits a reduced level of nicotine. However, genetic engineering of tobacco plants for the purpose of reducing nicotine levels is known in the art, and such methods have reduced nicotine in tobacco (specification, paragraph bridging pages 1 and 2).

Finding of *prima facie* obviousness

Rational and Motivation (MPEP 2142-43)

18. Therefore, it would have been *prima facie* obvious for one skilled in the art at the time of the invention to apply glucose oxidase to genetically modified tobacco plants to further reduce the levels of nicotine to a non-addictive level.

19. From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in practicing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

20. Claims 21-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Musser et al. as applied to claims 1, 2 and 5-20 above.

Applicant claims:

21. The Applicant claims a tobacco plant treated with glucose oxidase sufficient to reduce the levels of nicotine to non-addictive levels.

Determination of the scope and content of the prior art

(MPEP 2141.01)

22. The teachings of Musser et al. are described above.

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

23. Musser et al. do not teach a tobacco plant wherein the levels of nicotine have been sufficiently reduced to levels of nicotine that are non-addictive when consumed by the user. However, Musser et al. teach a tobacco plant where the leaves have been contacted by glucose oxidase resulting in 26% reduction in nicotine levels in the plant leaves. To determine the number of treatments, or the amount of glucose oxidase required to reduce the nicotine levels in the plant would require routine experimentation.

Finding of *prima facie* obviousness

Rational and Motivation (MPEP 2142-43)

24. Therefore, it would have been *prima facie* obvious for one skilled in the art at the time of the invention to produce a tobacco plant that has been contacted by sufficient glucose oxidase to reduce the nicotine levels to those that are non-addictive when consumed by a user.

25. From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention, because obtaining a tobacco plant with non-addictive levels of nicotine through contact with sufficient glucose oxidase would have required routine experimentation. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

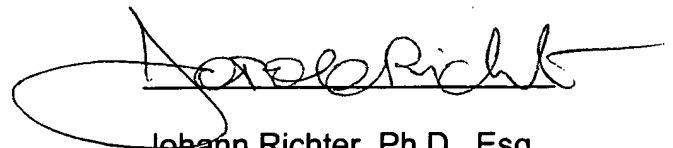
Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nathan W. Schlientz whose telephone number is 571-272-9924. The examiner can normally be reached on 8:30 AM to 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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